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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,770	12/17/2001	Yoshihito Ikeda	F-7178	2012

28107 7590 05/29/2003
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EXAMINER
PRATS, FRANCISCO CHANDLER

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 05/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/018,770	IKEDA ET AL.	
	Examiner	Art Unit	
	Francisco C Prats	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-18 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

The amendment filed December 17, 2001, has been received and entered.

Claims 1-18 are pending and are examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, during the translation into English, the claims have been rendered grammatically confusing, and therefore indefinite. In claim 1, at lines 9 and 10, the recitation "the one" is grammatically confusing and therefore indefinite. Also, it is not clear what property (a) is intended to mean.

Similarly, in claims 1, 3, 17 and 18 the recitation "peaks of analogues" is not clear in its meaning. There do not appear to be any analogues recited in any of the claims. Rather, the claims recite a combination of lecithin-derived superoxide

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dismutase (SOD) and a carrier which may be sucrose. Thus, it is not clear what the term "analogue" is referring to in any of the claims, including claim 3. Moreover, it is respectfully submitted that it is simply unclear what claim 3 is intended to mean.

The recitation "making sucrose coexist" in claims 17 and 18 is also indefinite. The claims appear to be directed to compositions comprising the combination of sucrose and lecithin-derived SOD. However, the recitation requiring "coexistence" merely requires sucrose and lecithin-derived SOD to exist at the same time, which is entirely different. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered

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therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-15, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 9-117279 in view of JP 1-304882.

JP '279 discloses the preparation of the claimed lecithin-derived SOD for therapeutic uses. See English language abstract. JP '279 differs from the cited claims in not combining the SOD derivative with a carrier which allows for the storage properties recited in the claims. However, JP '882 clearly discloses that combination of SOD with sucrose results in a stable SOD preparation suitable for storage. See English language abstract. Thus, the artisan of ordinary skill seeking to store the SOD derivatives of JP '279, recognizing from JP '882 that addition of sucrose would improve the storage stability of the SOD derivatives, clearly would have been motivated by JP '882 to have combined the SOD derivatives of '279 with sucrose to have rendered them stable for storage. A reasonable expectation of success would have been based on the fact that JP '882 discloses that the very same enzyme was rendered storage stable by combination with sucrose. A holding of obviousness is therefore required.

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Claims 1, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 9-117279 in view of JP 1-304882, and in further view of Kinoshita et al (U.S. Pat. 5,762,929).

As discussed above, JP '279, when taken in view of JP '882, clearly suggests the claimed combination of ingredients. Neither reference appears to disclose or suggest the claimed treatment of motor neuron disease or gastrointestinal ulcerative injury. However, Kinoshita clearly discloses that lecithin-derived SOD is suitable for use in treating both conditions. See abstract; see also column 1, lines 64-65. Thus, the artisan of ordinary skill at the time of applicant's invention clearly would have been motivated by Kinoshita to have used sucrose-stabilized, lecithin-derived SOD, as suggested to JP '279 and JP '882, in the treatment of motor neuron disease or gastrointestinal ulcerative injury. The claims must therefore be considered obvious under § 103(a).

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner

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can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Francisco C Prats
Primary Examiner
Art Unit 1651

FCP
May 20, 2003